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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,604	08/18/1999	RAGUPATHY MADIYALAKAN	AREX-P03-004	6693

7590 11/16/2004
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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/376,604

Applicant(s)

MADIYALAKAN ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 243,244 and 248-250 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 113,117-120,123,125,129-135,137-139,141-144,170-174,180-182,185,187,190-195,197-204,206-209,235-239,241,242-244, 248-251 and 254-257.

Continuation of Disposition of Claims: Claims rejected are 113,117-120,123,125,129-135,137-139,141-144,170-174,180-182,185,187,190-195,197-204,206-209,235-239,241,242,251 and 254-257.

MADIYALAKAN *et al.*

Date of priority: 06-17-1997

Request for Continued Examination

The request filed on 09-07-04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/376,604 is acceptable and a RCE has been established. The amendments filed 05-19-04 were entered. An action on the RCE follows.

Claims 243-244, and 248-250 remain withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 113, 117-120, 123, 125, 129-135, 137-139, 141-144, 170-174, 180-182, 185, 187, 190-195, 197-204, 206-209, 235-239, 241-242, 251, 254-257 are currently under consideration.

Rejections Maintained:

Claims 113, 117-120, 123, 131-135, 137-139, 141-144, 170-174, 180-182, 185, 190, 193-195, 197-204, 206-209, 235-239, 241-242, and 251 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,532,159 (Webb *et al.* April 1, 1994) for the reasons of record and for the reasons set forth below.

To reiterate, applicants have argued (Remarks, 05-19-04) that the prior art's "anti-OFP" antibodies are fundamentally different because the prior art does not specifically teach that a

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humoral or cell-mediated immune response took place following the injection of the antibodies. Applicant's point to the example (Figure 1) in the patent wherein the therapeutic effects of the anti-OFP antibodies indicated that tumor volume began to decrease after one day of treatment with the antibodies. Applicants argue that the rapid anti-tumor response of the antibodies (i.e. only 1 day until effects were seen) against the tumor indicated that no humoral or cell-mediated immune response could have occurred because, according to basic immunology, both responses must take more than one day to occur. However, as set forth previously (Advisory Action, 06-07-04), this argument has been considered but is not found persuasive. Furthermore, disclosed examples and preferred embodiments do not necessarily constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). For example, the methods illustrated in Figure 1 of the patent were preformed in a "nude" mouse, e.g., one that lacked a fully competent immune system. Thus, it would be difficult to observe the normal physiological and immunological effects that occur with the humoral and cell-mediated response. Hence, applicant arguments are not entirely relevant because the prior art example does not adequately parallel the scope of the claims. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 113, 117-120, 123, 125, 129-135, 137-139, 141-144, 170-174, 180-182, 185, 187, 190-195, 197-204, 206-209, 235-239, 241-242, 251, 254-257 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Baum *et al.* (Hybridoma, Vol. 12, No. 5, 1993, pages 583-589) or Madiyalakan *et al.* (Hybridoma, Volume 14, No. 2, May 19, 1995) in further view of US Patent

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No. 5,532,159 (Webb *et al.* April 1, 1994) for the reasons of record the actions mailed 09-25-03, 03-15-04, and 06-07-04.

Claims 190, and 238 also remain rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an antibody which is "non-human" (Claim 190) has no clear support in the specification and the claims as originally filed. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

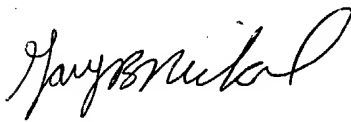
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



GARY NICKOL
PRIMARY EXAMINER